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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,477

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Torsten Branderburger

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10/23/2009

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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

NOTIFICATION DATE

DELIVERY MODE

10/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No. 10/550,477	Applicant(s) BRANDERBURGER ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 September 2009 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782).

6. Regarding claim 1, Strobel discloses a connector for packings containing medical liquids, particularly infusion, transfusion or enteral bags (col. 1, lines 5-10, 39-47, cols. 64-6, Fig. 1, system 1), comprising:

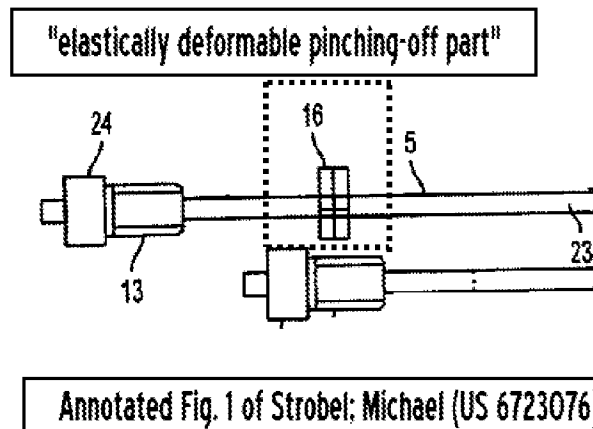
7. a connecting part with a passage which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 4, lines 38-40, col. 5, lines 30-34, Fig. 1, delivery tube 5);

8. a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 5, lines 1-5, 21-29, Fig. 1, cap 24);

9. characterized in that the connecting part has an elastically deformable pinching-off part (portion of delivery tube 5; see annotated Fig. 1 of Strobel);

10. which re-assumes its original shape again after being pinched by a pinching device (col. 5, lines 62-67, Fig. 1, clamp 16 deforming delivery tube 5, which later re-assumes its original shape); and

11. a pinching-off part that merges into a base part which widens to both sides and which can be integrated in the packing (col. 5, lines 14-21, delivery tube 5 connected to opening 22, depicted as having a larger diameter and therefore widened to both sides).



12. Strobel discloses the invention substantially as claimed, see above. However, Strobel discloses only that delivery tube 5 is capable of transferring fluid, and does not describe the specific cross-section shape. Therefore Strobel

lacks a noncircular axial cross section as claimed [1]. Imer discloses a resealable satchet for liquids (col. 1, lines 5-11, col. 2, lines 61-68, Fig. 1, satchet 1), comprising:

13. a connecting part (col. 3, lines 2-15, Fig. 1, opening strap 4);
14. with a passage (col. 3, lines 2-15, Fig. 1, outlet channel 3.1); and
15. a pinching-off part (col. 3, lines 20-27, Fig. 1, folding line 7);
16. that is designed as a tubular portion with a noncircular axial cross section that is different in two mutually perpendicular directions (col. 3, lines 28-31, portion of strap 4 near folding line 7 having substantially flat and noncircular axial cross section).
17. Imer solves the problem of containing and dispensing liquid from a bag with a resealable connection. Both Strobel and Imer dispense liquid through tubing attached to a bag, and use clamping mechanisms. Strobel applies clamp 16 to the outside of tube 5

(col. 5, lines 56-61), and Imer holds a folded portion of opening strap 4 within holding slit 6 (col. 3, lines 20-27).

18. Imer effectively clamps the portion of opening strap 4 within slit 6, to hold fluid within inner section 3 (col. 45, lines 12-18, especially lines 18-19, fold preventing leaks). A flat shape, or noncircular axial cross section prevents leaks through a clamped tube, since both surfaces of the tube contact each other when closed. In other words, a noncircular axial cross section is adapted for repeated clamping. One would be motivated to modify Strobel with the noncircular axial cross section as taught by Imer to hold fluid in a clamped state since Strobel calls for repeatedly clamping delivery tube (col. 5, lines 56-67, selective coupling to injection system). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel as discussed with the noncircular axial cross section as taught by Imer in order to provide tubing or a connecting part adapted for clamping and resealing.

19. Regarding claims 2 and 10, Strobel discloses:

20. [2] a closure part and connecting part secured with a snap fit (col. 5, lines 21-29, cap 24 for closing tube 5); and

21. [10] a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 1, lines 5-10, bag for fluid medications or nutrients).

22. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782), further in view of Fowles; Thomas A. et al. (US 4632267).

23. Regarding claim 3, Strobel and Imer disclose the invention substantially as claimed, see above. However, Strobel discloses that connectors 12 and 13 are luer or twist-type connectors (col. 4, lines 54-60, col. 5, lines 30-34), therefore Strobel and Imer lack a self-sealing membrane as claimed [3].

24. Fowles discloses a connector for packings containing parenteral and peritoneal dialysis liquids (col. 1, lines 4-17, col. 2, lines 50-58, Figs. 1-3, port system); comprising:

25. a connecting part with a passage (col. 2, lines 50-58, Fig. 1, port 13 having lumen);

26. which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 2, lines 66-3, Fig. 1, opening 22 for needle or other access means);

27. a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 2, lines 50-58, Fig. 1, closure 10);

28. [3] a self- sealing membrane arranged between the connecting part and the closure part that can be pierced by the spike for withdrawal of the liquid (col. 2, lines 59-66, Fig. 1, partition wall 20 dividing tubular bore 18 into upper bore 19 and lower bore 21; Examiner interprets the wall 20 as substantially “between” a connecting part and closure part, since it is narrower than the lumens of both closure 10 and port 13. additionally, wall 20 is between closure 10 and the lower bore 21 of port 13).

29. Fowles provides a connecting part adapted to be repeatedly pierced with a needle. Both Strobel and Fowles provide a detachable cap (cap 24 of Strobel and closure 10 of Fowles) at the end of a connecting part (delivery tube 5 of Strobel and port 13 of Fowles). Withdrawal needles are commonly interchanged as Luer-type connectors. That is, systems that couple lumens with Luer connectors or a membrane and needle are commonly interchanged. Additionally, a needle-membrane system preserves sterility by preventing contaminants from entering the outlet of a bag.

30. One would be motivated to modify Strobel and Imer with the self-sealing membrane as taught by Fowles to preserve the contents of a dispensing bag since Strobel calls for an adapter that is connected intermittently and excludes contaminants (col. 6, lines 43-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel and Imer as discussed by substituting a needle-membrane system of Fowles for the Luer connectors of Strobel in order to couple to dispensers commonly used in the art, while excluding contaminants.

31. Regarding claim 5, Strobel and Imer disclose the invention substantially as claimed, see above. However, Strobel and Imer lack an annular break zone as claimed [5]. Fowles discloses:

32. a closure part having a cap-shaped bottom part which is adjoined via an annular break zone (col. 3, lines 49-58, Fig. 2, scored line 150);

33. by a top part that can be broken off (Fig. 3, detached portion of closure 110).

34. Here, Fowles seals a cap initially before a user can withdraw fluid from a container. That is, the container is tamper-evident since scored line 150 is broken when first removing fluid from the container. Afterwards, the user can reseal the connector by replacing closure 10 on port 12. Fowles shows whether a container has been opened, and prevents contaminants from reaching the exterior surface of a piercing membrane. One would be motivated to modify Strobel and Imer with the annular break zone and top part as taught by Fowles since Strobel calls for a sealing cap 24 placed on adapter 13.

35. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Burns (US 5494170).

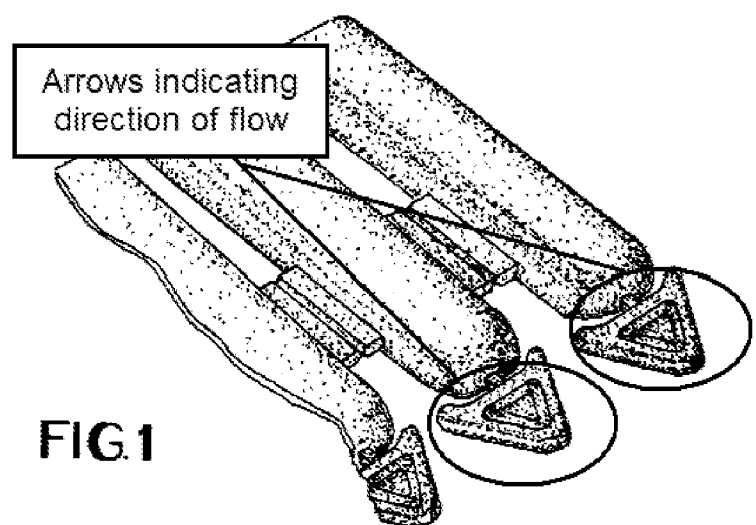
36. Regarding claim 4, Strobel, Imer and Fowles disclose the invention as substantially claimed, see above. However, Strobel, Imer and Fowles lacks clamping with elastic deformation between a connecting part and a closure part as claimed [4]. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit), further comprising a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals. Additionally, holding a membrane with elastic deformation allows a different material to be used for a

sealing membrane which may be more adaptable for repeated piercing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel, Imer and Fowles as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple withdrawals.

37. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of LeMarr et al. (US D456,507).

38. Regarding claims 6-8, Strobel, Imer and Fowles disclose the invention as substantially claimed, see above. However, Strobel, Imer and Fowles lack a flat grip piece and an arrow designed as a recess and/or as a raised structure as claimed [6-8].

LeMarr discloses a nebulizer vial comprising a flat grip piece and an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1 below). LeMarr provides the advantage of showing a user where fluid will exit a container when opened.



Annotated Fig. 1 of LeMarr et al. (US D456507)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel, Imer and Fowles as discussed with the arrow as taught by LeMarr in order to instruct a user.

39. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Knierbein (US 6364143).

40. Regarding claim 9, Strobel, Imer and Fowles disclose the invention substantially as claimed, see above. However, Strobel, Imer and Fowles lack a boat shape as claimed [9]. Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape). Knierbein provides the advantage of effectively draining a liquid container. For example, a boat shape drains contents of a bag effectively when inverted. One would be motivated to modify Strobel, Imer and Fowles with the boat shape as taught by Knierbein to drain a liquid container effectively.

Response to Arguments

41. Applicant's arguments, see p. 4-8 filed 10 September 2009 with respect to the rejection(s) of claim(s) 1-10 under 35 USC § 102 and 103 over Fowles, Knierbein Burns and LeMarr have been fully considered and are persuasive. Therefore, the rejection

has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Strobel, Imer, Fowles, LeMarr, Knierbein and Burns.

42. Applicant contends that Fowles fails to anticipate claim 1, namely an elastically deformable pinching-off part with a noncircular axial cross-section that is different in two mutually perpendicular directions, which can be pinched with a pinching device.

Examiner notes that Fowles instead teaches a connecting part with a circular axial cross section. Examiner cites Imer as teaching a noncircular axial cross-section in the new grounds of rejection.

43. Applicant submits that Fowles teaches away from the claimed pinching off part, since Fowles teaches a connector that is sealed during construction and describes a closure part that is "overmolded" to the connecting part port during construction such that once it is removed, it "prevent[s] the closure from being easily reinserted into the port." (Fowles 1:64-2:5). Examiner cites Strobel as teaching an elastically deformable pinching off part in the new grounds of rejection.

44. Applicant contends that Burns, LeMarr and Knierbein fail to remedy the deficiencies of Fowles, namely the pinching off part. Examiner cites Burns as teaching a snap fit and a self-seating membrane, cites LeMarr as teaching a flat piece and arrow designed as a recess and/or as a raised structure, and cites Knierbein as teaching a base part designed in the shape of a boat.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Smith; Daniel B. et al. US 7594578
- ◆ Domkowski; John et al. US 6280431
- ◆ Steer; Peter L. et al. US 4854737
- ◆ Muller; Charles B. US 4641362

46. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
Tel 571-272-2590
Fax 571-273-2590

47. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
21 October 2009